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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,662	12/01/2003	Rikard Holmdahl	10223-007001	2350

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,662	HOLMDAHL ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 11-20* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/430,278.

Claims 1, 2, 5-10 have been canceled.

New claims 16-21 have been added.

Claims 3, 4 and 9-21 are currently pending.

The following represent NEW GROUNDS of rejection not necessitated by Applicant's amendment. In view of the new grounds of rejection, this Office Action is made NON-FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 14 and 16-18 are rejected under 35 U.S.C. 102(a,e) as being clearly anticipated by U.S. Patent No. 7,063,847 to Sanderson et al. (A on form PTO-892).

The '847 patent teaches a composition comprising a molecular adjuvant. The molecular adjuvant comprises a segment of the complement C5a polypeptide and an amino acid segment of a hepatitis B virus protein that is a defined CTL epitope less than 200 amino acids in length (column 27, line 55 to column 33, line 58 in particular). The prior art teaching clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 3 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,063,847 to Sanderson et al. (A on form PTO-892) in view of Oshima et al (Immunol. Lett. [1998] 60:7-12; U on form PTO-892).

The '847 patent has been discussed supra.

The '847 patent does not specifically teach bacterial amino acid segmentss.

Oshima teaches that the botulinum neurotoxin (BoNT) produced by the bacterium *Clostridium botulinum* is the most toxic substance known (page 7 in particular). Oshima teaches a group of 17 BoNT peptides of less than 200 amino acids in length that are antibody and T cell epitopes (Table 2 in particular). Oshima teaches that these peptides generate antibodies cross-reactive with the c-terminal portion of BoNT, as well as with other clostridial toxins (Abstract in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '847 patent with the teachings of Oshima in order to construct a composition comprising a molecular adjuvant which contains C5 segment and an BoNT epitope peptide. One would have been motivated to combine these teachings by the well-known toxicity of BoNT and the paucity of effective vaccines in light of the teachings of the '847 patent that "Ag-specific responses to well-defined T cell and B cell epitopes observed in our studies support the potential use of YSFKPMPLaR (SEQ ID NO:1) and other response-selective C5a agonists as molecular adjuvants for inducing a defined spectrum of humoral and/or cellular responses against peptide, protein, and, possibly, non-protein Ags. Such a possibility would provide a broad-based adjuvant/delivery technology that would be applicable to a number of infectious and oncologic diseases in either prophylactic or therapeutic settings."

3. Claims 15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,063,847 to Sanderson et al. (A on form PTO-892) in view of Na et al (Clin Diag Lab. Immunol. [1999] 6(3):429-433; V on form PTO-892).

The '847 patent has been discussed supra.

The '847 patent does not specifically teach fungal amino acid segments, particularly maltose binding protein (MBP) amino acid segments.

Na teaches that the fungus *Candida albicans* is medically important because it causes severe candidiasis in immunocompromised patients and has a higher mortality rate than bacterial septicemia (page 429 in particular). Na teaches the presence of an antibody epitope in the extracellular aspartic proteinase of *Candida albicans* at amino acid residues 77-103, which is less than 200 amino acid residues in length (Abstract in particular). Na teaches that antibodies to this region have diagnostic value because they are not cross-reactive with other Candida species or with cathepsin D (Abstract in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of the '847 patent with the teachings of Na in order to construct a composition comprising a molecular adjuvant which contains C5 segment and a fungal epitope peptide. One would have been motivated to combine these teachings with a reasonable expectation of success by the teachings of the '847 patent that "Ag-specific responses to well-defined T cell and B cell epitopes observed in our studies support the potential use of YSFKPMPLaR (SEQ ID NO:1) and other response-selective C5a agonists as molecular adjuvants for inducing a defined spectrum of humoral and/or cellular responses against peptide, protein, and, possibly, non-protein Ags. Such a possibility would provide a broad-based adjuvant/delivery technology that would be applicable to a number of infectious and oncologic diseases in either prophylactic or therapeutic settings." Further, one could use the C5-based molecular adjuvant methods of the '847 patent to generate human antibodies to the Candida epitope taught by Na for in vivo diagnostic purposes that can be used without the danger of generating a human-anti-mouse antibody response.

Conclusion

4. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 21, 2007

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER